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Award Number: W81XWH-11-2-0167

TITLE: Framework for Smart Electronic Health Record ï Linked Predictive Models to Optimize Care for Complex Digestive Diseases

PRINCIPAL INVESTIGATOR: Dr. Ganesh Veerappan

CONTRACTING ORGANIZATION: Henry M. Jackson Foundation for the Advancement of Military Medicine
Rockville, MD 20852

REPORT DATE: June 2012

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
01-06-2012	Annual	1 Jul 2011 - 30 May 2012

4. TITLE AND SUBTITLE

Framework for Smart Electronic Health Record – Linked Predictive Models to Optimize Care for Complex Digestive Diseases

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-11-2-0167

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Henry M. Jackson Foundation for the Advancement of Military Medicine
Rockville, MD 20852

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Abstract on next page.

15. SUBJECT TERMS

None.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	11	19b. TELEPHONE NUMBER *(include area code)*

14. ABSTRACT

Our objective is to utilize de-identified database constructed from the world-wide Military electronic medical record for datasets (constructed for clinical purpose and not research) specific to patients with Crohn's disease (CD) and acute pancreatitis (AP). Using this collected data, we will develop Bayesian Network (BN) models to predict defined outcomes in CD and AP (death, surgeries, hospitalizations, etc). Once our model is developed, we hope to apply the model to an outside institution, specifically University of Pittsburgh, who will be performing a simi project with the hopes of testing their model on our de-identified database. The goal would be to identify specific clinical history that would l able to accurately predict severity and morbidity associated with these gastrointestinal diseases.

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Introduction:

Complex disorders result from the interaction of genetic, metabolic, and environmental factors that may not be themselves produce disease but can combine to alter disease severity and its progression. These factors, which may be contained in an electronic medical record (EMR) system, can be used to build predictive models of disease with the hope of improving disease management.

It is difficult to find these factors in EMR systems as the information is in both structured and unstructured formats that have been collected over many years. Research studies, in contrast, only collect a limited snapshot of a patient's clinical history. This information is usually not rich enough to develop predictive models. To construct a useful patient profile for analysis requires collecting disease progression and treatment information from a wide variety of sources that may span a decade or more.

Our study goal is to search our world-wide military electronic medical record for datasets for patients with Crohn's disease and acute pancreatitis. Using this collected data, we will develop Bayesian Network (BN) models to predict defined outcomes in CD and AP (death, surgeries, hospitalizations, etc.) Once our model is developed, we hope to apply the model to an outside institution, specifically University of Pittsburgh, who will be performing a similar project with the hopes of testing their model on our de-identified database. The goal would be to identify specific clinical history that would be able to accurately predict severity and morbidity associated with these gastrointestinal diseases.

Body:

During the past year we have spent the majority of time getting the protocol through the IRB process at Walter Reed. The IRB process was a long process, but we finally got approval from the IRB with exempt protocol status (Appendix A). IRB was approved locally and then a secondary review was performed at Medical Research & Material Command Human Research Protections Office. Patient also received approval through TMA and Kennell Associates (Appendix B). None of the data extraction could be performed until the study had final approval, which just occurred at the beginning of July.

In anticipation of approval, we have met multiple times with Kennell Associates, who will be performing the data extraction for these cohorts. We have set up parameters for searching for our cohorts and discussed mechanisms for identifying many of the variables that we hope to be studying. We also had a useful meeting at the University of

Pittsburgh in April 2012 to share ideas and make sure data will easily be shared and de-identified between institutions.

On the following page are the tasks accomplished and the upcoming tasks we hope to accomplish in the coming year.

Task	Y1Q1	Y1Q2	Y1Q3	Y1Q4	Y2Q1	Y2Q2	Y2Q3	Y2Q4	Status
HMJ Contracts with Kennell, Ms. Maydonovitch (Task1)									Completed
Submit IRB Protocol (Task1)									Completed
Scientific Review Committee (Task 1)									Completed
Protocol Approved (Task 1)									Completed
Secondary Approval at MRMC-HRPO (Task 1)									Completed
TMA Approval at Kennell and Associates (Task 1)									Completed
Meeting at University of Pittsburgh (Task 1)									Completed
Kick off with Kennell and Associates to begin data extraction, cohort definition (Task 2)									On schedule
Kennell will create datasets for Crohn's and pancreatitis patients (Task 2)									On schedule
Bayesian modeling developed at WR and Pitt (Task 3)									On schedule
Compare performance at other institutions. (Task 3)									On schedule
Present data and results									On schedule

Dark Green = Complete

Light Green = In progress

Yellow = Scheduled

KEY RESEARCH ACCOMPLISHMENTS: None to date

REPORTABLE OUTCOMES:

- Coordinated Research meeting for Walter Reed and Pittsburgh co-investigators in Pittsburgh on April 27, 2012

CONCLUSION:

The project has recently just received approval locally and at the secondary sites and we have laid down the groundwork to begin our extensive search of the military medical system for our cohorts. Once that data is extracted, we will perform Bayesian analysis and share our model with our collaborators at the University of Pittsburgh.

DEPARTMENT OF THE NAVY
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IN REPLY REFER TO

6500
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July 6, 2012

MEMORANDUM

From: WRNMMC DRP Determinations
To: LTC Ganesh Veerappan, MS, USA

Subj: WRNMMC DRP Determinations REVIEW OF 366706-1

PROJECT TITLE: [366706-1] The Use of Electronic Medical Record to Generate Bayesian Networks to Predict Patient Outcome in Patients with Crohn's Disease and Acute Pancreatitis

REFERENCE #:

SUBMISSION TYPE: New Project

ACTION: DETERMINATION OF EXEMPT STATUS

DECISION DATE:

1. Thank you for your submission of New Project materials for this research study. The WRNMMC DRP Determinations has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations in category 32 CFR 219.101.b4.

2. When you complete your research you must file a closure report.

3. You have been granted a partial HIPAA waiver from TMA dated 11 Jan 2012.

4. Any presentation or publications that arise from this project must go through appropriate publications clearance review.

5. Any changes to this protocol must be reviewed by this office to ensure the regulatory status of your protocol does not change.

6. If you have any questions, the POC is LTC Molly Klote at 301-295-8271 or mary.klote@med.navy.mil. Please include your project title and reference number in all correspondence with this committee.

This document has been electronically signed in accordance with all applicable regulations, and a copy is retained within our records.

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
HEALTH AFFAIRS
7700 Arlington Boulevard, Suite 5101
FALLS CHURCH, VIRGINIA 22042-5101

TRICARE
MANAGEMENT
ACTIVITY

28 March 2012

MEMORANDUM FOR: MAJ Ganesh R. Veerappan; Walter Reed National Military Medical Center, Bethesda

SUBJECT: Protocol Approval - Exempt

1. This is to advise that the Office of the Assistant Secretary of Defense for Health Affairs/TRICARE Management Activity (OASD HA/TMA), Human Subjects in Research Protection Office has completed its review of your protocol. We find that the following protocol is EXEMPT under 32 CFR 219.101(b)(4), in that it involves the secondary analysis of pre-existing, de-identified data. In this finding, we concur with the WRNMMC IRB determination dated 06 July 2012. **Approval from this office expires on 15 July 2014.**

a. **CDO Number: CDO-12-2024 (IRBNet # 366706)**
b. **Vendor Protocol Number**:
c. **Title:** The Use Of Electronic Medical Record To Predict Patient Outcomes In Patients With Crohn's Disease And Acute Pancreatitis
d. **Principal Investigator**: MAJ Ganesh R. Veerappan; Walter Reed National Military Medical Center, Bethesda
e. **PI email and phone:** ganesh.veerappan@med.navy.mil; 301-319-8743
f. **Government Project Manager (GPM)**: MAJ Ganesh R. Veerappan; Walter Reed National Military Medical Center, Bethesda
g. **GPM email and phone:** ganesh.veerappan@med.navy.mil; 301-319-8743

2. You are reminded that you must notify this office if the project is altered in any way (e.g. changes in location, investigators, sample size, age of subjects, changes to the consent form or methodology). You are further advised that it is your responsibility to ensure you and your associate investigators adhere to the guidelines of the protocol. You are also required to report any adverse events and actions taken to mitigate the events to the undersigned within 24 hours. Please be advised that although this protocol is rated as exempt, this office will periodically request an update on the status of the project. If applicable, protocol approval automatically expires when supporting contracting vehicle expires.

3. Please note if the project involves a survey or focus group, you may still need to submit your survey to Washington Headquarters Services (WHS) for approval and licensing under DoDD 8910.1 and/or to another agency (e.g. Office of Management and Budget) for approval. You

should contact these agencies for additional information prior to starting your study. Should you have any questions, please feel free to contact the undersigned at 703-681-1135.

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DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USPHS, cn=ECKERT.JOHN.J.1248350624
Date: 2012.07.25 09:58:18 -04'00'

John J. Eckert, PhD
CAPT, SCI, USPHS
Exempt Determination Official for HA/TMA
Human Research Protection Program